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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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GARDNER GROFF GREENWALD & VILLANUEVA. PC  
2018 POWERS FERRY ROAD  
SUITE 800  
ATLANTA, GA 30339

EXAMINER
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EASTWOOD, DAVID C

ART UNIT	PAPER NUMBER
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4185

MAIL DATE	DELIVERY MODE
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10/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,107	<b>Applicant(s)</b> GRIFFIN ET AL.	
	<b>Examiner</b> DAVID EASTWOOD	<b>Art Unit</b> 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/13/07 and 3/22/07</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 11-14 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Christine et al (US 3922099).

**Regarding Claim 11**, Christine Discloses an endcap which comprises a first end for attaching to a device (figure 5 item 31 and 32) and a second end defining an opening through which a sharp tip of a lancet can pass, the opening having a non-circular periphery comprising a plurality of inwardly and outwardly directed lobes. (Fig. 5 and 6, 6a and 6b)

**Regarding Claim 12**, Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including cross and star shapes. (Fig.5, 6, 6a, 6b)

**Regarding Claim 13**, Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations with smoothly rounded raised outer rims. (Fig.5, 6, 6a, 6b)

**Regarding Claim 14**, Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including a cross. (Fig.5, 6, 6a, 6b)

**Regarding claim 16**, Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations with smoothly rounded raised outer rims. (Fig.5, 6, 6a, 6b)

**Regarding Claim 17**, Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations with sharp lobes. (Fig.5, 6, 6a, 6b)

**Regarding Claim 18**, Christine discloses a single lobed non-planer sharply pointed distal tip. (Fig 5 item 24, 25, 26)

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al (US 5951493) in view of Christine et al (US 3922099).

**Regarding claim 1**, Douglas et al discloses a device for expressing body fluid from an incision in which it is well known and capable of moving a lancet from a first position to a second position and back to the first. (Column 6 Lines 56-68 and Column 7 lines 1-3) It is also well known and capable of positioning the lancet outside the body of said device in order to puncture the skin. (Fig. 3)

What Douglas et al does not disclose is a *non-circular periphery in the opening of the outer body of the housing comprising a plurality of inwardly and outwardly directed lobes*.

However Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including cross and star shapes. (Fig.5, 6, 6a, 6b)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Douglas et al with the planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including cross and star shape teachings of Christine et al in order to create a bulge in the donor site to facilitate the drawing of blood.

**Regarding claim 2**, Douglas et al fails to disclose that the periphery *of the opening is non- planar*

However Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including cross and star shapes. (Fig.5, 6, 6a, 6b)

It would have been obvious to one of ordinary skill in the art at the time of invention that modifying the invention of Douglas with the variously directed lobes in multiple configurations and surface textures including cross and star shapes teachings of Christine would create a bulge in the donor site to facilitate the drawing of blood.

**Regarding claim 3**, Douglas et al fails to disclose a raised rim around the opening.

However Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations with smoothly rounded raised outer rims. (Fig.5, 6, 6a, 6b)

It would have been obvious to one of ordinary skill in the art at the time of invention that modifying the invention of Douglas with the variously directed lobes in multiple configurations with smoothly rounded raised outer rims teachings of Christine would create a bulge in the donor site to facilitate the drawing of blood.

**Regarding claim 4**, Douglas fails to disclose the device *wherein the opening is generally cross-shaped, comprising four lobes*.

However Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including a cross. (Fig.5, 6, 6a, 6b)

It would have been obvious to one of ordinary skill in the art at the time of invention that modifying the invention of Douglas with the planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including a cross teachings of Christine would create a bulge in the donor site to facilitate the drawing of blood and increase the contact surface area.

**Regarding claim 5**, Douglas fails to disclose the device wherein the opening is generally star-shaped, comprising five lobes.

Douglas et al's invention as modified by Christine discloses the claimed invention except for an opening with a five lobed star. It would have been obvious to one having ordinary skill in the art at the time the invention was made to fabricate the opening with five lobes since the examiner takes Official Notice of the equivalence of a six lobed patterned opening for its use in the lancet art and the selection of any of these known equivalents to increase the contact surface area would be within the level of ordinary skill in the art.

**Regarding Claim 6**, Douglas fails to disclose the device wherein the lobes are smoothly-rounded.

However Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations with smoothly rounded raised outer rims. (Fig.5, 6, 6a, 6b)

It would have been obvious to one of ordinary skill in the art at the time of invention that modifying the invention of Douglas with the teachings of Christine would create a bulge in the donor site to facilitate the drawing of blood.

**Regarding Claim 7**, Douglas discloses the device except for wherein the lobes comprise teeth with sharp points.

However Christine et al discloses planer and non-planer openings with variously directed lobes in multiple configurations with sharp lobes. (Fig.5, 6, 6a, 6b)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Douglas's invention with the planer and non-planer openings with variously directed lobes in multiple configurations with sharp lobes teachings of Christine. In order to create a surface that would be unfamiliar or distracting to the patient.

**Regarding claim 8**, Douglas fails to disclose the device comprising at least one outwardly-projecting, non-planar lobe having a sharply-pointed distal tip.

However Christine discloses a single lobed non-planer sharply pointed distal tip. (Fig 5 item 24, 25, 26)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Douglas et al's invention with the single lobed non-planer sharply pointed distal tip teachings of Christine in order to create a bulge in the donor site to facilitate the drawing of blood and increase the contact surface area.

**Regarding Claim 10**, The device disclosed by Douglas et al has an inner dimension smaller than the corresponding outside dimension of the lancet preventing said lancet from becoming stuck in the opening. (fig. 3, 4, 5, and 6)

4. Claim 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Christine et al (US 3922099) in view of Douglas et al (US 5951493).



**Regarding Claim 15**, Christine et al's invention as modified by Douglas discloses the claimed invention except for an opening with a five lobed star. It would have been obvious to one having ordinary skill in the art at the time the invention was made to fabricate the opening with five lobes since the examiner takes Official Notice of the equivalence! of a six lobed patterned opening for its use in the lancet art and the selection of any of these known equivalents to increase the contact surface area would be within the level of ordinary skill in the art.

5. Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al (US 5951493) in view of Christine et al (US 3922099), as applied to claims above, and further in view of Chelak et al (US 6558402).

**Regarding Claim 9**, Douglas et al discloses a device for expressing body fluid from an incision in which it is well known and capable of moving a lancet from a first position to a second position and back to the first. (Column 6 Lines 56-68 and Column 7 lines 1-3) It is also well known and capable of positioning the lancet outside the body of said device in order to puncture the skin. (Fig. 3)

What Douglas fails to disclose is *an endcap for a lancing device, said endcap comprising a first end for connection to the lancing device, and a second end defining an opening through which a sharp tip of a lancet can pass, the opening having a non-circular periphery comprising a plurality of inwardly and outwardly directed lobes.*

However Christine et al Discloses an endcap which comprises a first end for attaching to a device (figure 5 item 31 and 32) and a second end defining an opening through which a sharp tip of a lancet can pass, the opening having a non-circular

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periphery comprising a plurality of inwardly and outwardly directed lobes. (Fig. 5 and 6, 6a and 6b)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Douglas et al with the planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including cross and star shape teachings of Christine et al in order to create a bulge in the donor site to facilitate the drawing of blood.

What Douglas et al's invention as modified by Christine et al failed to disclose is *a portion of the outer body housing near the opening comprises a transparent material.*

However, Chelak et al discloses there lancet device where indication marks of the position of stylet stop are visible through nose portion notch or window. The notch suitably has a translucent lens covering the notch. The lens magnifies the setting of the device, which is visible through notch. The setting is adjusted by the user and indication marks are marked on a portion of adjustment collar so as to provide an indication to the user of the depth penetration of the stylet.(Column 7 lines 58 – 66)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Douglas et al's invention as modified by Christine with the teachings of Chelak et al in order to increase the visibility of the donor site.

6. Claim 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Christine et al (US 3922099) in view of Douglas et al (US 5951493) and Chelak et al (US 6558402).

**Regarding Claim 19**, Christine et al Discloses an endcap which comprises a first end for attaching to a device (figure 5 item 31 and 32) and a second end defining an opening through which a sharp tip of a lancet can pass, the opening having a non-circular periphery comprising a plurality of inwardly and outwardly directed lobes. (Fig. 5 and 6, 6a and 6b)

What Christine et al fails to disclose is *a lancing device for collecting a sample of body fluid from a sampling site on the skin of a subject, said lancing device comprising an outer body housing and a lancet, the lancet being movable between a first position within the outer body housing and a second position wherein at least a sharp tip portion of the lancet extends through an opening in the outer body housing.*

However, Douglas et al discloses a device for expressing body fluid from an incision in which it is well known and capable of moving a lancet from a first position to a second position and back to the first. (Column 6 Lines 56-68 and Column 7 lines 1-3) It is also well known and capable of positioning the lancet outside the body of said device in order to puncture the skin. (Fig. 3)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Christine et al with the device for expressing body fluid from an incision in which it is well known and capable of moving a lancet from a first position to a second position and back to the first. (Column 6 Lines 56-68 and Column 7 lines 1-3) It is also well known and capable of positioning the lancet outside the body of said device in order to puncture the skin. (Fig. 3), as disclosed by Douglas et al in order to increase the contact surface area with the donor site of the patient.

What Christine et al's invention as modified by Douglas et al failed to disclose is *a portion of the outer body housing near the opening comprises a transparent material.*

However, Chelak et al discloses there lancet device where indication marks of the position of stylet stop are visible through nose portion notch or window. The notch suitably has a translucent lens covering the notch. The lens magnifies the setting of the device, which is visible through notch. The setting is adjusted by the user and indication marks are marked on a portion of adjustment collar so as to provide an indication to the user of the depth penetration of the stylet.(Column 7 lines 58 – 66)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Douglas et al's invention as modified by Christine with the teachings of Chelak et al in order to increase the visibility of the donor site.

7. Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al (US 5951493) in view of Christine et al (US 3922099).

**Regarding claim 20,** Douglas et al discloses a device for expressing body fluid from an incision in which it is well known and capable of moving a lancet from a first position to a second position and back to the first. (Column 6 Lines 56-68 and Column 7 lines 1-3) It is also well known and capable of positioning the lancet outside the body of said device in order to puncture the skin. (Fig. 3)

What Douglas fails to disclose is *an endcap for a lancing device, said endcap comprising a first end for connection to the lancing device, and a second end defining an opening through which a sharp tip of a lancet can pass, the opening having a non-circular periphery comprising a plurality of inwardly and outwardly directed lobes.*

However Christine et al Discloses an endcap which comprises a first end for attaching to a device (figure 5 item 31 and 32) and a second end defining an opening through which a sharp tip of a lancet can pass, the opening having a non-circular periphery comprising a plurality of inwardly and outwardly directed lobes. (Fig. 5 and 6, 6a and 6b)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Douglas et al with the planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including cross and star shape teachings of Christine et al in order to create a bulge in the donor site to facilitate the drawing of blood.

The invention of Douglas et al as modified by Christine et al is **well known and capable of** being placed *against the skin so that the skin is in communication with the non-circular opening*; and once in communication with the skin *applying sufficient pressure on the lancing device to cause tension upon the skin within the non-circular opening; triggering the lancing device; and continuing to apply pressure upon the skin with the lancing device while fluid is extracted from the sampling site.*

**Regarding claim 22**, Douglas et al discloses a device for expressing body fluid from an incision in which it is well known and capable of moving a lancet from a first position to a second position and back to the first. (Column 6 Lines 56-68 and Column 7 lines 1-3) It is also well known and capable of positioning the lancet outside the body of said device in order to puncture the skin. (Fig. 3)

What Douglas fails to disclose is *an endcap for a lancing device, said endcap comprising a first end for connection to the lancing device, and a second end defining an opening through which a sharp tip of a lancet can pass, the opening having a non-circular periphery comprising a plurality of inwardly and outwardly directed lobes.*

However Christine et al Discloses an endcap which comprises a first end for attaching to a device (figure 5 item 31 and 32) and a second end defining an opening through which a sharp tip of a lancet can pass, the opening having a non-circular periphery comprising a plurality of inwardly and outwardly directed lobes. (Fig. 5 and 6, 6a and 6b)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Douglas et al with the planer and non-planer openings with variously directed lobes in multiple configurations and surface textures including cross and star shape teachings of Christine et al in order to create a bulge in the donor site to facilitate the drawing of blood.

The invention of Douglas et al as modified by Christine et al is **well known and capable of** *contacting a skin surface at or adjacent to a sampling site with an irregular lobed contact surface, wherein the step of contacting a skin surface at or adjacent a sampling site with an irregular lobed contact surface comprises contacting the skin surface with at least one outwardly- projecting, non-planar lobe having a sharply-pointed distal tip.*

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brown et al (US 4990154), Edie, Danny D. (US 5154908), Warner, Henry A (US 5154908), Duchon et al (US 5964718), Bonaldo, Jean M. (US 6171262), Lloyd et al. (US 6322574), Schraga, Steven (US 6322575), Sharma et al (US 6491709).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell Mckinnon can be reached on (571)272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/DAVID EASTWOOD/  
Examiner, Art Unit 4185

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